DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provides for an increased daily dosage of lasalocid in pasture cattle.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 96–298 that provides for the use of BOVATEC® (lasalocid sodium) Premix in cattle. The supplemental NADA provides for an increased daily dosage of lasalocid in pasture cattle. The supplemental NADA is approved as of July 25, 2001, and the regulations are amended in 21 CFR 558.311 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

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The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.311 is amended by adding paragraph (d)(7); in the table in paragraph (e)(1) by revising paragraphs (e)(1)(ix) and (e)(1)(xii); by revising paragraphs (e)(2)(iii) and (e)(3)(iii); and in paragraphs (e)(2)(iv) and (e)(3)(iv) by removing "200" and adding in its place "300" to read as follows:

§ 558.311 Lasalocid.

* * * * *

(d) * * *

(7) Each use in a free-choice Type C cattle feed as in paragraph (e)(1)(xii) of this section must be the subject of an approved NADA or supplemental NADA as provided in § 510.455 of this chapter.

(e)(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ix)		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed.	046573
*	*	*	*	*
(xii)		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day.	046573
.....		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain.	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 200 mg of lasalocid per head per day.	021930
*	*	*	*	*

(2) * * *

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(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

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(3) * * *

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

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Dated: 8/24/01

August 24, 2001.

cv0137

Claire M. Lathers

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